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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,825	04/30/2001	Andrew J Garman	3764-75	3737

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Nixon & Vanderhye
1100 North Glebe Road 8th Floor
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EXAMINER

BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 12/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/763,825

Applicant(s)

GARMAN ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on preliminary amendment dated 27 Feb. 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1 & 7. 6) ☐ Other:

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

2. The information disclosure statements filed 27 Feb. 2001 and 11 July 2001 have been considered and made of record.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the metes and bounds of the claim cannot be clearly determined. The only positively recited structure of the claimed device is "an injection wall" and "cell injection needle" projecting from the wall. The rest of the claim recites statement of intended use. The claim language includes recitations such as "material is injected", etc. However, the claim is devoid of any positively recited structure for injecting or extracting material. The instant claim merely recites the presence of a needle and nothing in cooperation

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with the needle for providing the intended injecting and/or extracting functions. Clarification and/or correction is requested.

In claim 2, while the claim recites the presence of a cell propulsion means, the claim is silent as to how this means structurally cooperates with the wall and needle recited in claim 1, if at all.

Claim 6 is indefinite for reasons similar to claim 1. Claim 6 appears to be merely claiming a conduit with an injection needle, an inlet and an outlet. How are the cells moved and/or how is material injected and/or extracted as recited in the claim in the absence of any positively recited structure for providing these intended functions?

In claim 7, while the device further includes a cell sensor, it is not clear how the cell sensor structurally cooperates with the rest of the claimed device. What structure of claim 1 is actuated by the sensor? How can a fixed hollow needle be actuated?

Claim 8 is indefinite for the same reasons set forth with respect to claim 7.

In claim 9, with respect to which positively recited structure of claims 8 or 1 is the sensor connected to prevent further cells from being impelled toward the needle?

In claim 10, in the absence of a positively recited structure for expulsion of cells, how or what does the sensor actuate to remove the cell?

In claim 12, while the claim recites "a non-cell piercing hollow structure", the claim also recites application of chemical or force; however, the claim fails to positively recite structure for application of chemical or force.

In claim 13, the "respective inlets and outlets" lack antecedent basis. Note, the language of claim 1 does not require that the device include inlets or outlets.

In claim 14, it is not clear how a cell can be pierced and material injected and/or removed by merely passing through a conduit which includes a needle. It appears that the device required to perform the method as claim requires additional structure to operated as intended by the claim language.

With respect to claim 15, it is not clear how cells can be passed through the device of claim 1 in view of the structure recited in claim 1. Claim 1 merely recites a wall and a needle.

Claim 16 provides for the use of a needle, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 16 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Regarding claim 16, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 17 is indefinite because it is considered a hybrid claim. That is, the claim recites "An integrated cell process device" and states that the device includes the device of claim 1 combined with "one or more process or analysis steps". It is not clear which statutory class of invention (Apparatus or process) is intended to be covered by the instant claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 11, 12, 15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Leighton et al.(WO 91/05519).

The reference of Leighton et al. discloses a device and method of use which includes an injection wall (22) and a cell injection needle (24) projecting from the wall. The device includes a device (32, 23, 26) for impelling cells toward the needle. With respect to claims 11 and 12, Figures 4-6 depict the use of hollow or solid needles. Additionally, page 13, lines 9-17, discloses the use of electroporation as a means to transfer the material into the cells. The needle merely carries the material to be carried into the cell by electroporation. With respect to claim 15, page 9, lines 15-25, discloses the use of a suspension of cells.

7. Claims 1, 2, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Trimmer et al.(WO 96/10630).

The reference of Trimmer et al. discloses a device and method of use which includes an injection wall (14) and a cell injection needle (12) projecting from the wall. The device includes a device (20) for impelling cells toward the needle. With respect to claim 16, the figures

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discloses a needle of decreasing diameter and a tip portion of 0.05 to 10 microns (See page 7, lines 35-36).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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11. Claims 3-5, 13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leighton et al.(WO 91/05519).

The reference of Leighton et al. has been discussed above.

Claims 3-5 and 13 differ by specifically reciting that the device includes inlets and outlets and a plurality of cell processing chambers.

Page 10, line 6, to page 11, line 14, discusses the use of a suspension of cells and the use of cross flushing. The reference is silent as to the structure which provides this function.

However, the use of inlets and/or outlets to provide a suspension of cells to a chamber and/or provide a flushing solution is known in the art. As a result, it would have been obvious to one of ordinary skill in the art to provide the device of the primary reference with inlets and outlets for the known and expected result of providing a means recognized in the art for providing a suspension of cells and/or a flushing liquid. The use of a single structure as an inlet and outlet would have been merely an obvious matter in design choice while minimizing construction costs.

With respect to the use of plural chambers, based merely on the number of cells to be processed, it would have been obvious to one of ordinary skill in the art to provide parallel and/or serial chambers for the known and expected result of processing a large number of cells without scaling-up the device and/or allow one to process different sizes of cells by using chambers of different sizes of wells.

Finally, with respect to the needle size, it would have been obvious to one of ordinary skill in the art to determine the optimum needle size based merely on the size of the cell to be treated while minimizing the damage to the membrane of the cell.

Allowable Subject Matter

12. Claims 6 and 14 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

13. Claims 7-10 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

14. The following is a statement of reasons for the indication of allowable subject matter:

Claims 6 and 14 would be allowable because the prior art of record fails to teach or fairly suggest a conduit which includes a cell injection needle wherein the cells enter the conduit through an inlet, contact the injection needle and then move through an outlet of the conduit.

With respect to claims 7-10, the prior art of record fails to teach or fairly suggest the use of a cell sensor which determines the presence of a cell on or near the injection needle and injection or extraction of material with respect to the cell is controlled in response to the cell sensor.


Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Warden can be reached on 703-308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.


William H. Beisner
Primary Examiner
Art Unit 1744

WHB
December 11, 2002